

Application Serial No. 10/035,863  
Attorney Docket No. ZM0683/Implex-13

### REMARKS

Upon entry of this response, claims 1, 15, 21, 22 and 25-36 are pending. Claims 1 and 15 have been amended; claims 37-49 have not been entered. Support for the amendments can be found in the specification and drawings.

In the office action mailed September 8, 2005, the examiner:

- rejected claims 1, 15, 25, 29, 35 and 36 under 35 U.S.C. § 103(a) as unpatentable over U.S. Patent No. 6,030,390 to Mehdizadeh ("the Mehdizadeh patent") in view of U.S. Patent No. 5,308,350 to Mikhail ("the Mikhail patent");
- rejected claims 21, 22 and 26-34 under 35 U.S.C. § 103(a) as unpatentable over the Mehdizadeh patent in view of the Mikhail patent, and further in view of U.S. Patent No. 6,648,985 to Burkus et al ("the Burkus patent");
- noted that newly presented claims 37-49 would not be considered at this time because they depend from independent claim 1, which is not being allowed in the current Office Action.

### Claims 1, 15 and 21-36

Claims 1, 15 and 21-36 stand rejected under 35 U.S.C. § 103(a) as unpatentable over the Mehdizadeh patent in view of the Mikhail patent.

Claim 1 has been amended to recite:

"An instrument system for preparing a disc space between adjacent vertebral bodies . . . comprising:  
at least one distractor including:  
a tapered body section for distracting the vertebral bodies in a manner that restores natural lordosis . . . the tapered body section formed by:

PTN131444.1

Application Serial No. 10/035,863  
Attorney Docket No. ZM0683/Implex-13

an end wall; [and]  
a first pair of opposing wall portions converging toward the  
end wall; . . .  
a connector section opposite the body section . . . and  
a base portion connecting the tapered body section to the connector  
section;  
wherein said tapered body section has a length that is substantially  
greater than a length of said base portion such that when said distractor is  
inserted between the adjacent vertebral bodies the first pair of opposing  
wall portions engage the adjacent vertebral bodies to obtain said natural  
lordosis."

Claim 15 has been amended to recite:

"A distractor for use in a system that prepares a disc space between  
adjacent vertebral bodies . . . comprising:  
a tapered body section for distracting the vertebral bodies in a manner  
that restores natural lordosis . . . the tapered body section formed by:  
an end wall; [and]  
a first pair of opposing wall portions converging toward the  
end wall;  
a connector section opposite the body section . . . and  
a base portion connecting the tapered body section to the connector  
section;  
wherein said tapered body section has a length that is substantially  
greater than a length of said base portion such that when said distractor is  
inserted between the adjacent vertebral bodies the first pair of opposing  
wall portions engage the adjacent vertebral bodies to obtain said natural  
lordosis."

Independent claims 1 and 15 are patentable over the Mehdizadeh and Mikhail patents  
because those references, taken either alone or in combination, fail to disclose, teach or suggest  
all of the limitations of the claims. Specifically, neither the Mehdizadeh or Mikhail patents  
disclose, teach or suggest "said tapered body section has a length that is substantially greater than  
a length of said base portion such that when said distractor is inserted between the adjacent  
vertebral bodies the first pair of opposing wall portions engage the adjacent vertebral bodies to

PTN131444.1

Application Serial No. 10/035,863  
Attorney Docket No. ZM0683/Implex-13

obtain said natural lordosis," as required by claims 1 and 15. Rather, the Mehdizadeh disc space spreader 27, which is shown in position in Fig. 10, engages the adjacent vertebral bodies 25, 30 via the opposing *parallel* surfaces of the spreader. (See the Mehdizadeh patent, col. 3, lines 43-50 and Fig. 10.)

Moreover, even if the wedge sections of the Mehdizadeh disc spacer spreaders were engaged with the bone, their wedge angles (of from between 25-degrees to 45-degrees) are many times greater than any natural lordosis (identified in the instant application paragraph 31, lines 4-6, as being about 7 degrees in one exemplary embodiment) in either the lumbar or cervical spine. See the Mehdizadeh patent, col. 2, lines 37-41; col. 3, lines 5-8, 23-25; col. 4, lines 31-34, 39-47, 49-53; and Figs. 1B, 4 and 8.) Applicants note that, contrary to the suggestion of the examiner, the Mehdizadeh patent is devoid of any mention that the shape of its disc space spreader is for distracting the vertebral bodies in a manner that restores natural lordosis of the lumbar and cervical spines. The provision of the Mehdizadeh patent cited by the examiner in support of this proposition – column 3, lines 4-31 - does not even mention the term "lordosis." Furthermore, and as previously noted, even if the vertebral end plates were to rest on the surfaces of the wedges 12, 31, 46, "natural lordosis" would not be restored because the wedge angles are from between 25-degrees to 45-degrees.

The Mikhail patent fails to remedy the above noted deficiencies, because it is directed to a rod-shaped femoral distractor 120, 160. (See the Mikhail patent, col. 8, lines 56-61; col. 10, lines 56-60; and Figs. 18, 23.)

Application Serial No. 10/035,863  
Attorney Docket No. ZM0683/Implex-13

**Claims 21, 22 and 36-34**

Claims 21, 22 and 36-34 stand rejected under 35 U.S.C. § 103(a) as unpatentable over the Mehdizadeh patent in view of the Mikhail patent, and further in view of the Burkus patent. Claims 21, 22 and 26-28 depend upon claim 1, while claims 29-34 depend upon claim 15. As stated above in relation to independent claims 1 and 15, the Mehdizadeh and Mikhail patents, either alone or in combination, fail to disclose, teach or suggest "said tapered body section has a length that is substantially greater than a length of said base portion such that when said distractor is inserted between the adjacent vertebral bodies the first pair of opposing wall portions engage the adjacent vertebral bodies to obtain said natural lordosis," as required by claims 1 and 15. The Burkus patent fails to remedy this deficiency, because its distractor tips 56, 58, 356, 386, 726, like the Mehdizadeh distractor, are configured to engage the adjacent vertebra on opposing parallel surfaces 60, 61; 90, 91; 360, 361. (See the Burkus patent, col. 5, lines 64-66; col. 6, lines 28-30; col. 13, lines 59-65; col. 19, lines 6-10; Figs. 1b, 1c; 2b, 2c; 23a; 37.) The Burkus patent does not disclose that its distractor tips can be used to restore natural lordosis.

In view of the foregoing amendments and remarks, Applicant submits that this application is in condition for allowance. Early notification to that effect is respectfully requested. Should there be any questions or matters whose resolution may be advanced by a telephone call, the examiner is cordially invited to contact applicants' undersigned attorney at his number listed below.

PTN131444.1

Application Serial No. 10/035,863  
Attorney Docket No. ZM0683/Implex-13

A fee of \$450.00 for a two-month extension of time in responding to the current office action is believed due. The Commissioner for Patents is hereby authorized to charge this petition fee, as well as any other required fees, to deposit account 50-2061.

Respectfully submitted,



Paul A. Schwarz  
Registration No. 37,577

Dated: 01/27/2006

**DUANE MORRIS LLP**  
P.O. Box 5203  
Princeton, NJ 08543-5203  
(609) 631-2446 (Telephone)  
(609) 631-2401 (Fax)